

13 July 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99D-0557


To Whom It May Concern:

Food and Drug Administration (FDA) guidelines issued April 6, 1999 instituted a de facto ban on nonhuman primate xenografts because they would expose patients and the public to "significant infectious disease risk." But these guidelines failed to address dangers with other species. Transgenic pigs are the source animals of choice for xenotransplants despite the existence of over 25 diseases in pigs that can affect humans. Pigs are not safer than nonhuman primates: witness swine influenza, the Porcine Endogenous Retroviruses, paramyxovirus, and the new "Nipah" virus in Malaysia that infected over 250 humans, killed 100, and led to the slaughter of some 1 million pigs.

There are safer, more cost-effective, and humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include investing heavily in preventative medicine programs to reduce the need for transplants of all kinds and increasing the pool of human organs.

I respectfully demand that the Department of Health and Human Services ban xenotransplantation from all nonhuman species immediately.

Sincerely,


Jim Reynolds
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99D-0557

C203



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